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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,518	07/29/2003	Sarah J. Liljegren	SALKINS.035C1	4937
20995	7590	04/17/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			BAUM, STUART F	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1638	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/630,518	Applicant(s) LILJEGREN ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,10-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,10,12-14,16,17 and 19-21 is/are rejected.
- 7) ☒ Claim(s) 11 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/29/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 2/3/2006 has been entered.
2. Claims 8, 10-14, and 16-21 including SEQ ID NO:1 are pending and are examined in the present office action.

Claims 1-7, 9, and 15 have been canceled.

Claims 16-21 have been newly added and are drawn to the elected invention.

3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8, 10, 12-14, 16-17, and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, and 12-14, are indefinite in the recitation "NEVERSHED gene". The sole designation of a DNA sequence by "NEVERSHED gene" is arbitrary and creates ambiguity in the claims. For example, the DNA sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different DNA sequence. If either event occurs, one's ability to determine the metes and bounds

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of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection.

Written Description

6. Claims 8, 10, 12-14 remain rejected and claims 16-17, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/3/2005. Applicant's arguments filed 2/3/2006 have been fully considered but they are not persuasive.

Applicants contend that the present claims are limited to the NEVERSHED gene which the inventors have fully disclosed in the specification (page 5 of Remarks, 5th paragraph). Applicants contend that the present application discloses two alleles of the NEVERSHED gene, *nev-2* and *nev-1*, both of which produce a mutant protein which prevents floral organ loss (paragraph bridging pages 5 and 6 of Remarks). Applicants contend that one of skill in the art would recognize that a mutation at amino acid 197 or N-terminal to amino acid 197 in the ARF GAP domain would achieve the desired phenotype. Applicants contend an alignment with other ARF GAP domains shows conserved amino acids. Applicants contend one of skill in the art would have no difficulty in identifying a large number of mutations that would inactivate the ARF GAP domain and thereby achieve the desired phenotype from the teachings of the specification (*Ibid*).

The Office contends Applicants have not fulfilled the written description requirement for the full scope of Applicants' broadly claimed invention. Applicants have only disclosed the nucleic acid sequence from Arabidopsis of SEQ ID NO:1 and two mutant alleles of the disclosed sequence. Applicants claims are drawn to any NEVERSHED gene which encompasses not only the NEVERSHED gene from Arabidopsis, but also all homologous NEVERSHED genes from all plants. The Office recognizes the value of an alignment of other ARF GAP domains which show the conserved amino acids in said domain, but, the Office asserts that ARF GAP domains are not unique to only the NEVERSHED gene. Therefore, to fulfill the written description requirement for Applicants' broadly claimed invention, Applicants are required to disclose a representative number of sequences encoding NEVERSHED proteins from a representative number of plants that when mutated in the ARF GAP domain produce the desired phenotype of preventing organ loss, and to disclose essential elements/domains that are characteristic to NEVERSHED proteins.

Applicants contend that as of the filing of the application, ARF GAP domains were known and had an assigned function (page 6 of Remarks, 1st full paragraph). Applicants contend this information can be used by one of skill in the art to determine additional mutations that will inactivate any ARF GAP domain.

The Office contends that identifying essential amino acids in the ARF GAP domain is not the issue holding up the fulfillment of the written description requirement, but rather a lack of disclosure of a representative number of sequences encoding NEVERSHED proteins from a representative number of plants that when mutated in the ARF GAP domain produce the desired phenotype of preventing organ loss, and to disclose essential elements/domains that are

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characteristic to NEVERSHED proteins. ARF GAP domains are not unique to the NEVERSHED protein and not all protein comprising an ARF GAP domain will produce the desired phenotype when their ARF GAP domain is mutated.

Applicants contend that compliance with written description is a fact based analysis and not a legal analysis, and therefore *University of California v. Eli Lilly and Co* case law is not relevant to the claims of this application because the fact patterns are different between *Lilly* and the present application (paragraph bridging pages 6 and 7 of Remarks). Applicants contend the present claims deal with inactivating an ARF GAP domain which is more predictable than mutating a gene to maintain protein activity. Applicants contend that *Lilly* case law is over twenty years old and that at the time the present application was filed there has been incredible advances in data concerning ARF GAP domains and the genomes of several species is available (*Ibid*). Applicants contend that even if *Lilly* were a per se rule of law, Applicants have satisfied both prongs, i.e., the disclosure of two mutations which constitute a representative number of NEVERSHED genes (page 7 of Remarks, 1st full paragraph).

The Office contends that *Lilly* case law is relevant to this case even if it is more than twenty years old. According to 35 U.S.C. 112 1st paragraph, Applicants are to be in possession of their invention at the time of filing. The Federal Circuit stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. (See *University of California v. Eli Lilly and Co*). As discussed above, Applicants have not fulfilled the written description requirements.

Scope of Enablement

7. Claims 8, 10, 12-14 remain rejected and claims 16-17, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preventing organ loss in a plant, wherein said organ is sepal, petal and/or stamens, comprising mutating the ARF GAP domain of a gene in said plant, wherein the nucleotide sequence of said gene comprises SEQ ID NO:1, does not reasonably provide enablement for a method of preventing organ loss in any plant comprising mutating the ARF GAP domain of any gene in said plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/3/2005. Applicant's arguments filed 2/3/2006 have been fully considered but they are not persuasive.

Applicants contend the presently amended claims are now limited to mutating the NEVERSHED gene in a plant (page 8 of Remarks, 2nd full paragraph). Applicants contend they have disclosed the genomic portions of NEVERSHED in Arabidopsis as SEQ ID NO:7 and the cDNA of NEVERSHED as SEQ ID NO:1. Applicants contend one of skill in the art may use the disclosed sequences as probes to isolate corresponding genes from other plants or to screen databases. Applicants contend the amended claims are limited to floral organs and not any organs (paragraph bridging pages 8 and 9).

The Office contends Applicants' claims are drawn to a method which comprises any NEVERSHED protein from any plant, wherein the ARF GAP domain comprises a mutation which prevents floral organs from abscising. The Office contends Applicants have only

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exemplified two alleles of an Arabidopsis NEVERSHED gene that produces the desired phenotype. The Office contends given the breadth of the claims, the state-of-the-art, and the unpredictability in the art as discussed in the previous office action mailed 11/3/2005, undue trial and error experimentation would be required by one of skill in the art to practice the claimed invention.

Applicants contend the level of predictability in the prior art as discussed above regarding the written description requirement is greater than typically found in biotech related applications, and the present claims are directed to a method of inactivating a known domain (page 9 of Remarks, 3rd full paragraph). Applicants contend guidance is provided in the working examples, in particular, two examples of mutant NEVERSHED protein (page 9 of Remarks, 4th full paragraph). Applicants contend the level of skill in the art is very high (page 10 of Remarks, 1st full paragraph). Applicants contend relatively little experimentation is required (page 10 of Remarks, 2nd full paragraph). Applicants contend the claims are reasonably narrow as they are limited to mutating the NEVERSHED gene which is disclosed in the application and limited to the phenotype of preventing floral organ loss (page 10 of Remarks, 3rd full paragraph).

The Office contends that only one NEVERSHED gene has been exemplified even though Applicants' method is drawn to all NEVERSHED genes from all plants. In addition, as stated in the previous office action mailed 11/3/2005, ARF GAP domains are not unique to NEVERSHED proteins, and that other proteins exist that comprise an ARF GAP domain and that said proteins are not involved in floral organ abscission (see pages 6 and 7 of the office action mailed 11/3/2005). Applicants have also not taught how one skilled in the art would identify and isolate all NEVERSHED genes from all plants. The Office acknowledges that some guidance is

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provided in the specification, but given the unpredictability in the art of identifying NEVERSHED proteins comprising ARF GAP domains that when mutated produce the desired phenotype, and given the lack of guidance for identifying and isolating all NEVERSHED proteins comprising an ARF GAP domain that can be mutated to produce the desired phenotype, and given the breadth of the claims, undue trial and error experimentation would be required by one of skill in the art to practice the claimed invention.

8. Claims 8, 10-14, 16-21 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method of preventing floral organ loss in a plant, comprising mutating the ARF GAP domain of a gene in said plant, wherein said gene comprises the nucleotide sequence of SEQ ID NO:1.

9. Claim 11 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

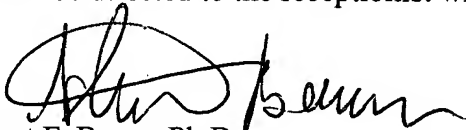
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.

Patent Examiner

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April 7, 2006

STUART F. BAUM, PH.D.
PATENT EXAMINER